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IN THE
Supreme Court of the United States

ALLERGAN, INC., and ALLERGAN SALES, INC.,
Petitioners,

v.

ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.;
ALCON UNIVERSAL, LTD.; and
BAUSCH & LOMB INCORPORATED,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether 35 U.S.C. § 271(e)(2) permits a patent holder to bring an infringement action upon the filing of an Abbreviated New Drug Application ("ANDA") "for a drug . . . the use of which is claimed in a patent," as the plain language of the statute states, or whether such an action can be brought only upon the filing of an ANDA "for a drug . . . the use of which is claimed in a patent *and is listed in the ANDA*," as the Federal Circuit ruled below.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iv

INTERESTS OF THE *AMICUS CURIAE* 1

STATEMENT OF THE CASE 2

REASONS FOR GRANTING THE PETITION 8

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW THREATENS ADVANCES IN HEALTH CARE BY UNDERMINING INCENTIVES TO DEVELOP NEW, LIFE-SAVING THERAPIES 9

A. Off-Label Uses of FDA-Approved Products Play a Crucial Role in Health Care, and Patents Covering Such Uses Should Be Enforceable to the Same Extent as Patents Covering FDA-Approved Uses 10

B. Review Is Warranted Because the Decision Below Upsets the Balance Congress Intended to Create When It Adopted the Hatch-Waxman Act 13

II. REVIEW IS WARRANTED BECAUSE THE APPEALS COURT'S DECISION CONFLICTS WITH THE PLAIN LANGUAGE OF § 271(e)(2) 15

CONCLUSION 18

TABLE OF AUTHORITIES

Page

Cases:

Buckman Co. v. Plaintiffs' Legal Committee,
531 U.S. 341 (2001) 10, 11
Eli Lilly and Co. v. Medtronic, Inc.,
496 U.S. 661 (1990) 16
Roche Products, Inc. v. Bolar Pharmaceuticals Co.,
733 F.2d 858 (Fed. Cir. 1984) 13
United States v. LaBonte,
520 U.S. 751 (1997) 15
Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003) 7, 9, 15, 17, 18
Washington Legal Found. v. Friedman,
13 F. Supp. 2d 51 (D.D.C. 1998),
appeal dism'd, 202 F.3d 331 (D.D.C. 2000) 1, 11

Statutes and Constitutional Provisions:

Drug Price Competition and Patent Term Restoration Act
(the "Hatch-Waxman Act"), Pub. L. 98-417,
98 Stat. 1585 (1984) 4, 8

Federal Food, Drug, and Cosmetics Act,
21 U.S.C. § 301, *et seq.* 3, 4
21 U.S.C. § 355a(a)(1)(i) 3
21 U.S.C. § 355(c)(3)(D)(ii) 3
21 U.S.C. § 355(j) 4, 13
21 U.S.C. § 355(j)(2)(A)(vii)(IV) 5, 14
21 U.S.C. § 355(j)(5)(B)(iii) 5, 6, 14
21 U.S.C. § 355(j)(7)(A) 5

Page

35 U.S.C. § 156 ..... 4, 14
35 U.S.C. § 271(e)(1) 4, 13
35 U.S.C. § 271(e)(2) ..... *passim*

Miscellaneous:

Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 FOOD & DRUG L.J. 71 (1998) 11

Sarah F. Jagger, Testimony before the House Government Reform Committee, Subcommittee on Human Resources, 1996 WL 520197 (F.D.C.H.) (Sept. 12, 1996) 11

U.S. General Accounting Office, *Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,* GAO/ PAMD-91-14 (Sept. 1991) 11

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Walsh,* 123 S. Ct. 1855 (2003). WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

WLF has appeared in numerous cases related to the proper resolution of drug patent disputes. *See, e.g., Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002) (Hatch-Waxman Act procedures for resolving drug patent disputes). WLF also filed a brief in this case when it was before the Federal Circuit.

WLF is concerned that the decision of the Federal Circuit, if allowed to stand, will significantly impair the ability of patent holders to file suit in federal court to protect their patents against infringement. There is no dispute that

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

Petitioners hold a valid method-of-use patent that covers a use for the drug brimonidine whose value is widely recognized within the medical profession; indeed, the evidence suggests that the patented use accounts for a significant majority of prescriptions written for the drug. Yet the Federal Circuit has held that Petitioners may not sue under the Hatch-Waxman Act to prevent competitors from inducing infringement of that patent.

WLF believes that the patent system is an important tool in providing pharmaceutical companies with the necessary financial incentives to gamble the substantial sums necessary for the development of new, life-saving therapies. WLF fears that the decision below significantly undermines those incentives.

WLF has no direct interest in the outcome of this case or any related cases. WLF takes no position on the underlying patent dispute between Petitioners (hereinafter "Allergan") and Respondents (hereinafter "Alcon" and "Bausch & Lomb"). WLF is filing this brief solely because it believes that the district court improperly applied the procedures established by the Hatch-Waxman Act for resolving pharmaceutical patent disputes.

WLF is filing with the consent of all parties. The written consents have been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

WLF hereby adopts by reference the Statement of the Case set forth in the Petition. In brief, this case involves a dispute between a pioneer drug manufacturer (Allergan) and two generic drug manufacturers (Alcon and Bausch & Lomb) regarding Alcon's and Bausch & Lomb's proposed sale of

brimonidine, a drug used to treat open-angle glaucoma, a disease of the eye. In September 1996, Allergan obtained Food and Drug Administration (FDA) approval for the manufacture and sale of brimonidine for the purpose of lowering intraocular pressure ("IOP") in patients with open-angle glaucoma. At the time that FDA approved Allergan's New Drug Application ("NDA"), it was generally thought within the medical profession that glaucoma was caused by abnormally high IOP, which pushed against -- and thereby damaged -- the optic nerve. Pet. App. 46a. Allergan marketed its product under the trade name Alphagan; the product soon became a leading drug to treat glaucoma. *Id.*

The Food, Drug, and Cosmetics Act (FDCA) grants the holder of an approved NDA a five-year period of exclusivity in marketing its drug. 21 U.S.C. § 355(c)(3)(D)(ii). Allergan's exclusivity period for brimonidine was extended for six months pursuant to 21 U.S.C. § 355a(a)(1)(i) (which permits extensions based on manufacturer testing of a product's safety and efficacy in children); thus, its exclusivity period expired in March 2002.

In recent years, the medical profession has changed its views considerably regarding the causes of glaucoma. Pet. App. 46a. Scientists discovered that patients with lowered IOP were still contracting glaucoma; they thus concluded that open-ended glaucoma is a neurodegenerative disease that originates in the optic nerve itself. *Id.* Accordingly, scientists began looking for ways to prevent glaucoma by treating the optic nerve directly, *i.e.*, neuroprotection.

In the early 1990s, researchers at Allergan discovered that brimonidine has significant neuroprotective properties; *i.e.*, the optic nerve and other nerve cells are rendered less susceptible to injury and degeneration when treated with

brimonidine. *Id.* at 47a. That discovery caused many doctors to conclude -- under the more recent view that glaucoma is a neurodegenerative disease -- that brimonidine is effective in treating glaucoma because of its neuroprotective qualities. Based on its discovery, Allergan obtained two method-of-use patents (the "'415 Patent" and the "'741 Patent") that claim a method of using brimonidine as a neuroprotective agent to treat glaucoma. *Id.* at 50a.

Alcon and Bausch & Lomb filed Abbreviated New Drug Applications (ANDAs) with FDA in October 2001, seeking permission to sell brimonidine (following the expiration of Allergan's exclusivity period) for use in reducing IOP. *Id.* Congress created the ANDA procedure in 1984 as part of the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j). The Hatch-Waxman Act was Congress's attempt to strike a balance between the competing interests of pioneer and generic drug manufacturers. The Act benefited generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act also benefited generic manufacturers by amending patent law to allow them to use patented products in connection with studies designed for the purpose of obtaining FDA approval of an ANDA; that amendment allowed generic manufacturers to begin product testing before expiration of the patent. 35 U.S.C. § 271(e)(1). The Act benefited pioneer manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. § 156.

The Act also set forth procedures for resolving patent disputes between pioneer and generic manufacturers. Those procedures are set forth in § 505(j) of the FDCA, 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of

FDA-approved drugs and to include on that list any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A). That FDA list is generally referred to as the "Orange Book." If a generic manufacturer seeks to market a generic version of an approved drug for which a patent is claimed in the Orange Book, the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[2]

An ANDA that includes a Paragraph IV Certification and that is otherwise proper must be approved immediately by FDA unless the patent holder files an infringement action within 45 days of the date on which the applicant notifies the patent holder that a Paragraph IV Certification has been filed. 21 U.S.C. § 355(j)(5)(B)(iii). If an infringement action is filed within that 45-day period, then the FDCA provides:

> [T]he approval [of the ANDA] should be made effective upon the expiration of the thirty-month period beginning on the date of the receipt [by the patent holder of notice of the Paragraph IV certification] or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –
>
> (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval should be made effective on the date of the court decision.

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[2] Such a certification is often referred to as a "Paragraph IV Certification."

Id.

As noted above, Alcon and Bausch & Lomb in October 2001 filed ANDAs seeking FDA permission to market brimonidine for the purpose of lowering IOP in open-angle glaucoma patients, in anticipation of the March 2002 expiration of Allergan's exclusivity period. Because Allergan had listed the '415 Patent and the '741 Patent in the Orange Book, Alcon and Bausch & Lomb included Paragraph IV Certifications in their ANDAs; those certifications indicated that the manufacture, sale, or use of their products would not infringe Allergan's patents because their products would be labeled only for use in lowering IOP, not for neuroprotection.

On January 9, 2002 -- within 45 days of receiving notice of Alcon's and Bausch & Lomb's Paragraph IV Certifications -- Allergan filed suit in federal district court under 35 U.S.C. § 271(e)(2). That section -- yet another provision added to federal law by the Hatch-Waxman Act -- establishes as "an act of infringement" the filing of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent," if the purpose of the ANDA is to obtain FDA approval for the manufacture, use, or sale of the drug "before the expiration of such patent." Allergan alleged that Alcon and Bausch & Lomb filed ANDAs not because they anticipated substantial sales for treatment of excessive IOP, but because they anticipated that many doctors would prescribe their products for neuroprotection. Allergan alleged that such prescriptions would infringe on its method of use patents, and that Alcon and Bausch & Lomb had already taken numerous actions designed to induce such infringement.

The district court granted summary judgment to Alcon, ruling that 35 U.S.C. § 271(e)(2) did not create a cause of action for Allergan's benefit. Pet. App. 45a-68a. The court

held that even accepting as true Allergan's allegation regarding Alcon's actions to induce infringement of Allergan's patents, Congress did not intend § 271(e)(2) to cover such situations. *Id.* The court later granted summary judgment to Bausch & Lomb on identical grounds.

In March 2003, the Federal Circuit affirmed, but it issued a highly unusual opinion. *Id.* 1a-44a. The three-judge panel's *per curiam* opinion held that the panel was bound by the interpretation of § 271(e)(2) set forth by a prior panel in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). *Warner-Lambert* had held in January 2003 that a method-of-use patent holder may not sue for patent infringement under § 271(e)(2) unless the alleged infringer has stated explicitly in its ANDA that it intends to market its product for the patented use. Although the panel felt bound by *Warner-Lambert* to affirm the dismissal of Allergan's § 271(e)(2) claim, all three panel members joined concurring opinions stating their beliefs that *Warner-Lambert* was wrongly decided and indicating that they would have reinstated Allergan's claims had they been free to do so. Pet. App. 22a-44a.

Judge Schall, joined by Judge Clevinger, stated in an opinion concurring in the judgment only, "In my view, contrary to the conclusion reached in *Warner-Lambert*, a claim of induced infringement like the one asserted by Allergan against Alcon and B&L is cognizable under 35 U.S.C. § 271(e)(2)." *Id.* at 22a (Schall, J., concurring in the judgment). Similar, Judge Linn stated, "In my opinion, the court in *Warner-Lambert* has ventured beyond our interpretive role and, in interpreting the complex statutory scheme before it, has allowed its policy choices and its evaluation of the legislative history -- reasonable as they may be -- to override

the terms of the statute chosen by Congress." *Id.* at 42a (Linn, J., concurring in the judgment).

REASONS FOR GRANTING THE PETITION

This case raises health care and patent issues of exceptional importance. If advances in health care are to continue, two competing interests must be properly balanced: (1) the public interest in a strong patent system that rewards innovation by providing exclusive marketing rights to those whose research and development expenditures result in the development of new therapies; and (2) the public interest in encouraging the marketing of generic versions of those new products (after expiration of an appropriate exclusivity period), thereby ensuring the competition necessary to produce lower prices. Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Hatch-Waxman Act. The decision below puts that balance seriously out of whack; the Court should grant review to restore the balance intended by Congress.

The language of § 271(e)(2) could not be plainer that a patent holder situated as is Allergan is permitted to file suit in federal court, based on claims that a generic drug manufacturer is inducing others to infringe the patent, whenever the generic manufacturer files an ANDA for a drug the use of which is covered in the patent. The Federal Circuit's refusal to enforce the statute as written appears to be based on the fact that the patented use for brimonidine is an off-label use (*i.e.*, Allergan's FDA-approved labeling for Alphagan does not include neuroprotection). But as this Court has repeatedly recognized, off-label use of FDA-approved products is a crucial component of the practice of medicine in this country. Often, the medical community recognizes that proper patient care *requires* the prescription of a drug for an off-label use; indeed,

the great majority of prescriptions written for brimonidine are written by doctors seeking to utilize its patented (but off-label) neuroprotective properties. By adopting a strained reading of § 271(e)(2) to deny a cause of action to pharmaceutical patent holders simply because the allegedly infringed use happens to be an off-label use, the Federal Circuit has significantly curtailed the ability of such patent holders to protect their property rights.

This diminution of patent rights in turn will have significant adverse health effects by reducing the incentive for companies to conduct the research necessary to develop new, life-saving therapies.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW THREATENS ADVANCES IN HEALTH CARE BY UNDERMINING INCENTIVES TO DEVELOP NEW, LIFE-SAVING THERAPIES

The Federal Circuit's refusal to permit Allergan and similarly situated patent holders to enforce their patent rights by bringing an action under § 271(e)(2) appears to have been based primarily not on the actual language of that statute, but rather on a belief that patents covering uses not approved by FDA are less worthy of protection than patents covering approved uses. *See, e.g., Warner-Lambert,* 316 F.3d at 1358 ("[I]f an innovator had not made the investment to test and obtain [FDA] approval of the new use, what investment is to be protected by creating an added incentive?"). That belief suggests that the Federal Circuit fails to appreciate the importance of off-label uses in health- care delivery and of the need to encourage research designed to discover such uses -- an importance recognized by this Court on several occasions.

Review is warranted because of the potential adverse health consequences of the decision below.

A. Off-Label Uses of FDA-Approved Products Play a Crucial Role in Health Care, and Patents Covering Such Uses Should Be Enforceable to the Same Extent as Patents Covering FDA-Approved Uses

When it approves a drug or medical device for introduction into interstate commerce, FDA reviews the product labeling. The labeling sets forth the indications approved by FDA. FDA requires such drugs or devices to bear labeling which lists their approved uses, and prohibits such labeling from listing any use that has not been approved by FDA. But FDA does not attempt to regulate the practice of medicine and thus does not attempt to regulate the uses doctors make of FDA-approved products. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 350-51 (2001).

Indeed, advances in medical care often stem from the discovery that new uses of FDA-approved drugs and devices can benefit patients otherwise lacking satisfactory treatment options. The medical community's knowledge regarding the safety and efficacy of FDA-approved products inevitably outpaces FDA-approved labeling. Physicians who regularly work with these drugs and devices, and researchers who study their utility in treating conditions or patient populations that are not included in the existing labeling, often learn that they can be used safely and effectively for purposes outside the labeling.

The diffusion of this knowledge can have important benefits for patients -- particularly patients faced with serious illnesses and few treatment options, or a range of treatment options that have already failed or proved unsatisfactory due

to low effectiveness or side effects that are hard to tolerate. In fields such as oncology, for example, a substantial number of medically-accepted treatments involve off-label uses of FDA-approved drugs.[3] Similarly, physicians have long relied extensively on off-label treatments in caring for patients with AIDS.[4] Were doctors limited to using FDA-approved products only as labeled, in many cases their patients would receive sub-optimal care.

The importance of off-label uses of FDA-approved products is by now universally accepted. Most importantly, both FDA and the Court have recognized the important role that off-label uses play in our health care system. *See, e.g., Buckman*, 531 U.S. at 351 n.5 ("'Off-label use is widespread in the medical community and often is essential to giving patients optimal health care, both of which medical ethics, FDA, and most courts recognize.'") (quoting Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 FOOD & DRUG L.J. 71, 72 (1998)). *See also, Washington Legal Found. v. Friedman,* 13 F. Supp. 2d at 56.

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[3] *See, e.g.*, U.S. General Accounting Office, *Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,* GAO/PEMD-91-14 (Sept. 1991) (finding that 25% of cancer drugs were used off-label and that 56% of cancer patients were given at least one drug off-label).

[4] *See, e.g.*, Testimony of Sarah F. Jagger, General Accounting Office Director of Health Services Quality and Public Health Issues, before the House Government Reform Committee, Subcommittee on Human Resources, 1996 WL 520197 (F.D.C.H.) (Sept. 12, 1996) (citing research finding that more than 80% of AIDS patients received at least one drug off-label and that 40% of all drugs that were given were prescribed off-label).

Information about safe and effective off-label uses of FDA-approved products does not materialize on its own. Rather, reliable information can be developed only through pains-taking and expensive medical research. Funding for such research is far more easily obtained if investors reasonably believe that they can derive an economic return from their investment in research. Indeed, that is precisely the theory underlying our patent system: the law provides an economic incentive for new product development by ensuring (by means of restrictions on competition) that firms that invest in research and development of new products -- or new uses of existing products -- will be able to realize a return on their investment when their research and development expenditures bear fruit.

The decision below significantly reduces those financial incentives. It deprives pharmaceutical patent holders of an important means of preventing infringement of their patents, based solely on the fact that the patent covers a method of use that FDA has not approved for inclusion on the labeling of an FDA-approved product. The effect of that decision is not difficult to discern: firms will now be substantially less willing to invest in research and development of new uses for existing pharmaceuticals, and (in the not-too-distant future) the flow of information about such new uses will be reduced substantially. Review is warranted to determine whether Congress really intended to create a two-tiered patent regime whereby patents covering one important aspect of our health-care delivery system (those covering off-label uses of FDA-approved products) are afforded less protection than patents covering other aspects of that system.

B. Review Is Warranted Because the Decision Below Upsets the Balance Congress Intended to Create When It Adopted the Hatch-Waxman Act

When it adopted the Hatch-Waxman Act (of which § 271(e)(2), the statute at issue in this case, is an integral part), Congress intended to strike a balance between the rights of pioneer and generic drug manufacturers, to ensure that strong incentives remained in place for the development of new, life-saving therapies. Review is warranted because the decision below threatens to upset that balance and thereby undermine incentives for continued health-care advances.

The Hatch-Waxman Act provided several significant benefits to generic drug manufacturers, benefits designed to increase competition in drug sales. Most significantly, the Act created the ANDA procedure, which allows companies to obtain FDA marketing approval for a generic drug without conducting their own extensive safety and efficacy studies. An ANDA allows a generic company to obtain marketing approval by piggybacking on the studies submitted by the pioneer manufacturer when it submitted its NDA. *See* 21 U.S.C. § 355(j). The Act also allows a generic company to conduct tests on a patented drug for the purpose of preparing an ANDA in anticipation of the patent's expiration. 35 U.S.C. § 271(e)(1). By so providing, the Act overruled *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that using a patented drug for testing in order to prepare an application for FDA marketing approval was an infringing use. Pet. App. 55a.

Congress was careful, however, to maintain incentives for new product development by including several provisions in the Hatch-Waxman Act that benefited pioneer manufacturers. For example, the Act granted patent term extensions as

partial recompense for the years lost at the front end of the patent. 35 U.S.C. § 156.[5] Most importantly for purposes of this case, the Act created a procedure allowing pioneer manufacturers to protect their patents by filing infringement actions (and obtaining injunctive relief) even before competing generic companies begin marketing their products. 21 U.S.C. § 355(j)(2) & (5); 35 U.S.C. § 271(e)(2). That procedure (outlined above in more detail at 5-6) is a significant benefit to pioneer drug manufacturers; an injunction that prevents infringing actions is always preferable to an award of damages (which may or may not be collectible) after the infringing actions have occurred.

The decision below upsets the balance created by Hatch-Waxman by depriving pioneer manufacturers of this patent-enforcement mechanism in a significant number of suits. Under the Federal Circuit's decision, generic manufacturers are permitted to: (1) piggyback on a pioneer manufacturer's research in order to apply for an ANDA; and (2) conduct tests on the pioneer manufacturer's product regardless of any patents on the drug; yet pioneer manufacturers may not take advantage of the Hatch-Waxman Act's patent enforcement mechanisms in a significant number of suits, regardless how much evidence they may have that the generic company plans to market the drug in a manner that will infringe existing patents or will induce others to do so. Congress struck the balance achieved in the Hatch-Waxman Act in part to ensure that the patent rights granted to pioneer drug companies were sufficiently strong to ensure continued high levels of drug research.

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[5] Drug patent holders generally must wait five or more years from the time they initially obtain a patent until they receive approval of their NDA from FDA and thus can begin marketing their drug. By the time that the NDA is approved, a significant portion of a patent holder's exclusive marketing period has elapsed.

Review is warranted because the Federal Circuit's decision threatens to upset that balance by depriving pioneer drug companies of significant patent enforcement rights, thereby substantially reducing incentives to engage in research designed to develop new, life-saving therapies.

II. REVIEW IS WARRANTED BECAUSE THE APPEALS COURT'S DECISION CONFLICTS WITH THE PLAIN LANGUAGE OF § 271(e)(2)

Review is warranted for the additional reason that the Federal Circuit's decision is so plainly at odds with the express language of 35 U.S.C. § 271(e)(2). Indeed, all three members of the panel agreed that Allergan had stated a cause of action under § 271(e)(2) but felt constrained by the Federal Circuit's prior decision in *Warner-Lambert* to hold otherwise. Pet. App. 22a-41a; *id.* 42a-44a. Direct splits among the federal appeals courts are, of course, nearly impossible in patent cases because of the Federal Circuit's exclusive appellate jurisdiction. But the virtually unprecedented situation presented by this case -- a three-judge appeals court panel unanimously expressing its disagreement with another panel from the same circuit on a clear-cut issue of law -- is as close to a circuit split on an issue of patent law as the Court is ever likely to see.

The Court has repeatedly made clear that the primary, if not the exclusive, basis for interpreting a federal statute is the plain meaning of the actual language employed by Congress. *United States v. LaBonte*, 520 U.S. 751, 757 (1997) ("[W]e assume that in drafting this legislation, Congress said what it meant."). Section 271(e)(2) provides as follows:

> It shall be an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission

> is to obtain approval under the [FDCA] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

If one parses each clause of § 271(e)(2), one searches in vain for a requirement (imposed by the Federal Circuit) that a method of use patent holder demonstrate that the patented use is explicitly listed in the generic competitor's ANDA. To the contrary, Allergan's complaint fulfilled each of the statute's prerequisites for stating a claim that Alcon and Bausch & Lomb committed infringing acts when they submitted their ANDAs. First, the ANDAs submitted by Alcon and Bausch & Lomb were for a drug (brimonidine) "the use of which is claimed in a patent" (the '415 and '741 Patents). Second, the ANDAs were submitted for the purpose of obtaining FDA approval to "engage in the commercial manufacture, use, or sale" of brimonidine. Third, a method of using the drug that Alcon and Bausch & Lomb intend to market is claimed in Allergan's patents. Finally, Alcon and Bausch & Lomb intend to market brimonidine as soon as their ANDAs are approved; thus, the manufacture, use, or sale of generic brimonidine obviously will occur long "before the expiration of [the '415 and '741] patent[s]," which will not expire for many years to come.[6]

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[6] The act of infringement created by § 271(e)(2) has been referred to as "a highly artificial act of infringement," because it involves nothing more than the filing of a document with the government, not the manufacture, sale, or use of a patented product. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Meeting the prerequisites of § 271(e)(2) is sufficient to allow a patent holder to get his foot inside the federal courthouse door; but in order to succeed in his § 271(e)(2) claim, the patent holder must demonstrate that the defendant has filed a Paragraph IV Certification "that is in error as to whether commercial

(continued...)

The *Warner-Lambert* panel arrived at a contrary interpretation only by giving a tortured reading to the language of § 271(e)(2). Pointing to the penultimate clause of that provision (". . . the use of which is claimed in a patent . . ."), the panel stated that Congress's choice of the words "the use" rather than the words "a use" suggests reference to a particular use; the panel concluded that "the use" being referred to is "the use listed in the ANDA." *Warner-Lambert*, 316 F.3d at 1356. That conclusion is silly. The panel is correct that the choice of "the" rather than "a" indicates that Congress had an antecedent in mind. But the language of the clause quite clearly ties the words "the use" to uses claimed in the patent, not to uses listed in the ANDA. Because the use of brimonidine for neuro-protective purposes is the use claimed by Allergan in its patent, because the Respondents have filed an ANDA to sell a drug (brimonidine) "the use of which is claimed in a patent," and because Allergan alleges that Respondents have filed their ANDA with the intent of inducing others to infringe Allergan's patent, Allergan has stated a cause of action under § 271(e)(2). As Judge Schall cogently explained in his opinion below concurring in the judgment, the Federal Circuit's contrary interpretation of § 271(e)(2) cannot be squared with the language of that provision. *See* Pet. App. 23a-25a.

The issue that divided the two Federal Circuit panels -- whether 35 U.S.C. § 271(e)(2) creates a cause of action for infringing or inducing infringement of patents covering off-

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[6](...continued)
manufacture, use, or sale of the new drug (none of which, of course has actually occurred) violates the relevant patent." *Id.* WLF takes no position on whether Allergan could make such a showing; but § 271(e) indicates that Congress intended to permit pioneer manufacturers to go before a district court in an effort to make such a showing.

label uses of FDA-approved products -- is a recurring one, as is evidenced by the nearly simultaneous consideration of the issue in two separate Federal Circuit cases. Because the *Warner-Lambert* panel happened to issue its decision more quickly, its decision has created the controlling precedent in the Federal Circuit. Because that decision is so clearly at odds with the statutory language and is likely to have significant impact on the delivery of health care in this country, review by this Court is warranted.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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